IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 13-2003-RGA
ALVOGEN PINE BROOK, INC.,	)	
Defendant.	)	

ANSWER AND COUNTERCLAIMS FOR DEFENDANT ALVOGEN PINE BROOK, INC.

Defendant Alvogen Pine Brook, Inc. ("Alvogen"), by and through its undersigned attorneys, hereby answers each of the numbered paragraphs of the First Amended Complaint, filed January 24, 2014 by Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK") and MonoSol Rx, LLC (individually "MonoSol") (collectively "Plaintiffs"). Except as expressly admitted below, Alvogen denies each allegation of Plaintiffs' First Amended Complaint.

NATURE OF THE ACTION

1. Alvogen admits that Plaintiffs purport to bring this action under the Food and Drug Laws and the Patent Laws of the United States. Alvogen further admits that Alvogen Pine Brook Inc. submitted ANDA No. 205954 to the Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j) to obtain approval to market buprenorphine hydrochloride and naloxone hydrochloride sublingual film ("the Alvogen product") prior to the expiration of United

States Patent Nos. 8,475,832 ("the '832 patent"), 8,017,150 ("the '150 patent"), and 8,603,514 ("the '514 patent") (collectively, "the patents-in-suit"). Alvogen denies the remaining allegations in paragraph 1.

THE PARTIES

2. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 and therefore Alvogen denies same.

3. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and therefore Alvogen denies same.

4. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 and therefore Alvogen denies same.

5. Alvogen admits the allegations in paragraph 5.

6. Alvogen admits the allegations in paragraph 6.

JURISDICTION AND VENUE

7. Alvogen does not contest that this Court has subject matter jurisdiction over this action.

8. Alvogen does not contest that this Court has personal jurisdiction over Alvogen Pine Brook Inc. for the purposes of this action. Alvogen denies the remaining allegations in paragraph 8.

9. Alvogen does not contest venue in this district for purposes of this action.

THE PATENTS-IN-SUIT

10. Alvogen admits that the '832 patent states that it issued on July 2, 2013. Alvogen admits that the '832 patent is entitled "Sublingual and Buccal Film Compositions." Alvogen admits that Garry L. Myers, Samuel D. Hillbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi,

and Madhusudan Hariharan are listed as inventors on the face of the '832 patent. Alvogen admits that Plaintiff RBP is listed as the assignee on the face of the '832 patent. Alvogen admits that a purported copy of the '832 patent is attached to the First Amended Complaint as Exhibit A. Alvogen denies that the '832 patent was duly and legally issued. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 10 of the First Amended Complaint and therefore denies them.

11. Alvogen admits that the '150 patent states that it issued on September 13, 2011. Alvogen admits that the '150 patent is entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom." Alvogen admits that Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz are listed as inventors on the face of the '150 patent. Alvogen admits that Plaintiff MonoSol is listed as the assignee on the face of the '150 patent. Alvogen admits that a purported copy of the '150 patent is attached to the First Amended Complaint as Exhibit B. Alvogen denies that the '150 patent was duly and legally issued. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11 of the First Amended Complaint and therefore denies them.

12. Alvogen admits that the '514 patent states that it issued on December 10, 2013. Alvogen admits that the '514 patent is entitled "Uniform Films for Rapid Dissolve Dosage Forms Incorporating Taste-Masking Compositions." Alvogen admits that Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz are listed as inventors on the face of the '514 patent. Alvogen admits that Plaintiff MonoSol is listed as the assignee on the face of the '514 patent. Alvogen admits that a purported copy of the '514 patent is attached to the First Amended Complaint as Exhibit C. Alvogen denies that the '514 patent was duly and legally

issued. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 12 of the First Amended Complaint and therefore denies them.

SUBOXONE® SUBLINGUAL FILM

13. Alvogen admits that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") entry identifies "Reckitt Benckiser" as the applicant for New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film. Alvogen lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 13 of the First Amended Complaint and therefore denies them.

14. Alvogen admits that the Orange Book identifies August 30, 2010 as the approval date for NDA No. 22-410 directed to the 2 mg/0.5 mg and 8 mg/2 mg dosages of Suboxone sublingual film. Alvogen admits that the labeling for Suboxone® sublingual film currently states that Suboxone® sublingual film is "indicated for maintenance treatment of opioid dependence." Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 14 of the First Amended Complaint and therefore denies them.

15. Alvogen admits that the '832, '150, and '514 patents are identified in the Orange Book for Suboxone® sublingual film. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15 of the First Amended Complaint and therefore denies them.

DEFENDANT'S ANDA

16. Alvogen admits that Alvogen Pine Brook, Inc. sent letters, dated October 25, 2013, and November 21, 2013, to Plaintiffs, and that such letters stated that ANDA No. 205954 contains a Paragraph IV certification stating that the '832 and '150 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 16 of the First Amended Complaint and therefore denies them.

17. Alvogen admits that it submitted ANDA No. 205954 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of the Alvogen product before expiration of the patents-in-suit. Alvogen admits that ANDA No. 205954 identifies the NDA for Suboxone® sublingual film as the Reference Listed Drug. To the extent that paragraph 17 of the First Amended Complaint contains additional allegations, Alvogen denies them.

18. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 of the First Amended Complaint and therefore denies them.

19. Alvogen admits that Alvogen Pine Brook, Inc. sent a letter, dated December 10, 2013, to Plaintiffs, and that such letter stated that ANDA No. 205954 contains a Paragraph IV certification stating that the '514 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 19 of the First Amended Complaint and therefore denies them.

20. Alvogen admits that it submitted ANDA No. 205954 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of the Alvogen product before expiration of the patents-in-suit. Alvogen admits that ANDA No. 205954 identifies the NDA for Suboxone® sublingual film as the Reference Listed Drug. To the extent that paragraph 20 of the First Amended Complaint contains additional allegations, Alvogen denies them.

21. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 of the First Amended Complaint and therefore denies them.

22. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 of the First Amended Complaint and therefore denies them.

COUNT I

(Infringement of the '832 Patent Under 35 U.S.C. § 271(e)(2))

23. Alvogen repeats and realleges its answers to paragraphs 1-22 as if fully set forth herein.

24. Denied.

25. Alvogen admits that it submitted ANDA No. 205954 with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j). Alvogen denies the remaining allegations in paragraph 25 of the First Amended Complaint.

26. Denied.

COUNT II

(Infringement of the '150 Patent Under 35 U.S.C. § 271(e)(2))

27. Alvogen repeats and realleges its answers to paragraphs 1-26 as if fully set forth herein.

28. Denied.

29. Alvogen admits that it submitted ANDA No. 205954 with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j). Alvogen denies the remaining allegations in paragraph 29 of the First Amended Complaint.

30. Denied.

COUNT III

(Infringement of the '514 Patent Under 35 U.S.C. § 271(e)(2))

31. Alvogen repeats and realleges its answers to paragraphs 1-30 as if fully set forth herein.

32. Denied.

33. Alvogen admits that it submitted ANDA No. 205954 with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j). Alvogen denies the remaining allegations in paragraph 33 of the First Amended Complaint.

34. Denied.

PRAYER FOR RELIEF

Defendant denies that Plaintiffs are entitled to any remedy or relief, including those requested in the First Amended Complaint.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or the truth of any allegation in Plaintiffs' First Amended Complaint, Defendant states the following affirmative defenses:

First Affirmative Defense

The claims of the '832, '150, and '514 patents are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of Sections 101, 102, 103, 111, 112, 116, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

Second Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of the Alvogen Product that is the subject of ANDA No. 205954 will not infringe, directly or indirectly, any valid and/or enforceable claim of the '832 '150, and/or '514 patents.

Third Affirmative Defense

The filing of ANDA No. 205954 has not infringed, and will not infringe, directly or indirectly, any valid and/or enforceable claim of the '832, '150, and/or '514 patents.

Fourth Affirmative Defense

Plaintiffs' First Amended Complaint fails to state a claim upon which relief may be granted.

Fifth Affirmative Defense

Defendant's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

COUNTERCLAIMS

For its counterclaims against Plaintiffs/Counterclaim-Defendants Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively "Counterclaim-Defendants"), Defendant/Counterclaim-Plaintiff Alvogen Pine Brook, Inc. ("Alvogen") alleges as follows:

THE PARTIES

1. Alvogen is a Delaware corporation having a principal place of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey.

2. On information and belief, as stated in its First Amended Complaint against Alvogen, RBP is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. On information and belief, as stated in its First Amended Complaint against Alvogen, RBP UK is a corporation organized and existing under the laws of the United Kingdom, having a principal place of business at 103-105 Bath Road, Slough, UK.

4. On information and belief, as stated in its First Amended Complaint against Alvogen, MonoSol is a limited liability corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 30 Technology Drive, Warren, New Jersey.

JURISDICTION AND VENUE

5. These counterclaims arise under the Patent Act, 35 U.S.C. §§ 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. To the extent that the Court has subject matter jurisdiction over Counterclaim-Defendants' claims against Alvogen, this Court has

subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over RBP because, among other reasons, it subjected itself to the jurisdiction of this Court by filing its First Amended Complaint against Alvogen.

7. This Court has personal jurisdiction over RBP UK because, among other reasons, it subjected itself to the jurisdiction of this Court by filing its First Amended Complaint against Alvogen.

8. This Court has personal jurisdiction over MonoSol because, among other reasons, it subjected itself to the jurisdiction of this Court by filing its First Amended Complaint against Alvogen.

9. To the extent that venue is appropriate for Counterclaim-Defendants' claims against Alvogen, venue is also appropriate in this Court for Alvogen's counterclaims. Venue is also proper in this judicial district under 28 U.S.C. § 1391(b) and (c).

10. There is an actual and justiciable controversy between the parties as to the infringement, validity, and enforceability of United States Patent Nos. 8,475,832 ("the '832 patent"), 8,017,150 ("the '150 patent"), and 8,603,514 ("the '514 patent").

BACKGROUND

11. Upon information and belief, as stated in its First Amended Complaint, RBP holds approved New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

12. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA

identifies these patents in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book").

13. The '832 patent, entitled "Sublingual and Buccal Film Compositions," states that it issued on July 2, 2013.

14. Upon information and belief, as stated in its First Amended Complaint, RBP UK claims to be the assignee of the '832 patent.

15. The '150 patent, entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom," states that it issued on September 13, 2011.

16. Upon information and belief, as stated in its First Amended Complaint, MonoSol claims to be the assignee of the '150 patent.

17. Upon information and belief, as stated in its First Amended Complaint, RBP claims to hold an exclusive license to the '150 patent.

18. The '514 patent, entitled "Uniform Films for Rapid Dissolve Dosage Forms Incorporating Taste-Masking Compositions," states that it issued on December 10, 2013.

19. Upon information and belief, as stated in its First Amended Complaint, MonoSol claims to be the assignee of the '514 patent.

20. Upon information and belief, as stated in its First Amended Complaint, RBP claims to hold an exclusive license to the '514 patent.

21. Upon information and belief, Counterclaim-Defendants, including MonoSol and RBP, caused the '832, '150, and '514 patents to be listed in the Orange Book as patents that claim the drug and/or claim a method of using such a drug for which RBP submitted NDA No. 22-410.

22. Alvogen submitted its ANDA No. 205954 to obtain FDA approval to engage in the commercial manufacture, use, and sale of the Alvogen Product before the expiration of the '832, '150, and '514 patents.

23. Alvogen's ANDA No. 205954 contains a "Paragraph IV" certification under U.S.C. § 505(j)(2)(A)(vii)(IV) that the claims of the '832, '150, and '514 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Alvogen Product.

24. On January 24, 2014, Counterclaim-Defendants filed their First Amended Complaint against Alvogen alleging infringement of the '832, '150, and '514 patents.

COUNT I

(Non-Infringement of the '832 Patent)

25. Alvogen repeats and realleges the allegations in paragraphs 1-24 above as if fully set forth herein.

26. The manufacture, use, sale, offer for sale and/or importation of the Alvogen Product will not infringe, directly or indirectly, any valid or enforceable claim of the '832 patent.

27. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, or importation of the Alvogen Product will infringe the '832 patent.

28. Alvogen is entitled to a judicial declaration that it has not infringed and does not infringe—literally or under the doctrine of equivalents, directly or indirectly, by inducement or contribution—any valid claim of the '832 patent.

COUNT II

(Non-Infringement of the ’150 Patent)

29. Alvogen repeats and realleges the allegations in paragraphs 1-28 above as if fully set forth herein.

30. The manufacture, use, sale, offer for sale, and/or importation of the Alvogen Product will not infringe, directly or indirectly, any valid or enforceable claim of the ’150 patent.

31. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, or importation of the Alvogen Product will infringe the ’150 patent.

32. Alvogen is entitled to a judicial declaration that it has not infringed and does not infringe—literally or under the doctrine of equivalents, directly or indirectly, by inducement or contribution—any valid claim of the ’150 patent.

COUNT III

(Non-Infringement of the ’514 Patent)

33. Alvogen repeats and realleges the allegations in paragraphs 1-32 above as if fully set forth herein.

34. The manufacture, use, sale, offer for sale, and/or importation of the Alvogen Product will not infringe, directly or indirectly, any valid or enforceable claim of the ’514 patent.

35. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, or importation of the Alvogen Product will infringe the ’514 patent.

36. Alvogen is entitled to a judicial declaration that it has not infringed and does not infringe—literally or under the doctrine of equivalents, directly or indirectly, by inducement or contribution—any valid claim of the ’514 patent.

COUNT IV

(Invalidity of the ’832 Patent)

37. Alvogen repeats and realleges the allegations in paragraphs 1-36 above as if fully set forth herein.

38. On information and belief, the claims of the ’832 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of Sections 101, 102, 103, 111, 112, 116, 132, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

39. There is an actual and justiciable controversy between the parties concerning whether the ’832 patent claims are invalid.

40. Alvogen is entitled to a judicial declaration that the claims of the ’832 patent are invalid.

COUNT V

(Invalidity of the ’150 Patent)

41. Alvogen repeats and realleges the allegations in paragraphs 1-40 above as if fully set forth herein.

42. On information and belief, the claims of the ’150 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of Sections 101, 102, 103, 111, 112, 116, 132, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

43. There is an actual and justiciable controversy between the parties concerning whether the ’150 patent claims are invalid.

44. Alvogen is entitled to a judicial declaration that the asserted claims of the ’150 patent are invalid.

COUNT VI

(Invalidity of the ’514 Patent)

45. Alvogen repeats and realleges the allegations in paragraphs 1-44 above as if fully set forth herein.

46. On information and belief, the claims of the ’514 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of Sections 101, 102, 103, 111, 112, 116, 132, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

47. There is an actual and justiciable controversy between the parties concerning whether the ’514 patent claims are invalid.

48. Alvogen is entitled to a judicial declaration that the asserted claims of the ’514 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Alvogen prays that the Court enter judgment in its favor and against Counterclaim-Defendants as follows:

a. Dismissing the First Amended Complaint with prejudice and denying each request for relief made by Plaintiffs;

b. Declaring that the filing of ANDA No. 205954 has not infringed, does not infringe, and would not infringe any valid and enforceable claims of the ’832, ’150, and/or ’514 patents;

c. Declaring that the manufacture, use, sale, offer for sale, and/or importation into the United States of the Alvogen Product that is the subject of ANDA No. 205954 does not, and will not, infringe any valid and enforceable claim of the '832, '150, and/or '514 patents;

d. Declaring that the claims of the '832, '150, and '514 patents are invalid;

e. Awarding Alvogen its costs and expenses in this action;

f. Awarding Alvogen its attorneys' fees pursuant to 35 U.S.C. § 285; and

g. Awarding other and further relief as this Court deems just and proper.

/s/ Jeffrey T. Castellano

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